

REMARKS

Claim Amendments

Claim 19, claims 20 and 36 that depend from claim 19, and added claims 41-42 are pending in this application. Claims 21-35 and 37-40 are withdrawn.

Applicants have amended claim 19 to remove the recitation of R₃ and R₉ as amino. Applicants have also amended Claim 20 to more clearly point out the claimed subject matter.

Applicants have added Claims 41-42. Support for new claim 41 can be found, for example, on p. 9, line 13 to p. 16, line 20 of the specification as originally filed. Support for new claim 42 can be found, for example, on p. 45, lines 8-13 of the specification as originally filed.

None of these amendments or new claims adds new matter.

Rejections

35 U.S.C. §102(b) - Anticipation

Claims 19-20 and 36 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Nishino et al., U.S. Patent 6,071,968 ("the '968 patent"). According to the Examiner, the '968 patent refers to compositions that are both oral and injectable. Specifically, the Examiner points out that when R₂ and R₃ of the subject application are H, and R₁ is alkyl, the '968 patent reads on the pending claims.

Applicants traverse. However, solely to expedite prosecution, applicants have amended claim 19 to remove the recitation of R₃ and R₉ = amino. The '968 patent requires a

para (applicants' positions R₃ and R₉) amino substitution in its Formula I. As amended, the claims of this application do not encompass compounds having an R₃ or R₉ (para) amino substitution. Thus, the '968 patent does not anticipate any of the compositions recited in the amended claims. Accordingly, the above amendment obviates the Examiner's rejection. Applicants request reconsideration.

35 U.S.C. §103(a) – Obviousness

Claims 19-20 and 36 stand rejected under 35 U.S.C. §103(a) as being allegedly obvious over Nishino et al., U.S. Patent 6,071,968 ("the '968 patent"). Specifically, the Examiner asserts that the '968 patent teaches structurally similar compounds and compositions, as recited in the pending claims, for administration orally or by injection. The Examiner acknowledges that the '968 patent "has not made exact compositions and have not made a composition using two or more compositions" as recited in the pending claims. Nevertheless, the Examiner asserts that it would have been obvious to one of ordinary skill in the art to obtain the claimed compounds and compositions. Applicants traverse this rejection to the extent that it is maintained over the claims as amended.

This obviousness rejection is based on alleged structural obviousness. It has improperly failed to consider the pharmaceutical activity of the claimed compounds. On that basis alone, the rejection should be withdrawn.

The pending claims recite a pharmaceutical composition that requires a compound and a pharmaceutically acceptable carrier, adjuvant, or vehicle. See, e.g., claim

19. The Technical Field of the Invention teaches that the claimed pharmaceutical compositions may be advantageously used as therapeutic agents for *inosine-5'-monophosphate dehydrogenase (IMPDH) mediated processes* (page 1, lines 9-12). Specifically, the application discloses that the claimed pharmaceutically acceptable compositions are useful as IMPDH inhibitors and can be used for the treatment or prophylaxis of transplant rejection and autoimmune disease (page 6, lines 5-11). The application also teaches that the claimed pharmaceutical compositions are useful as multi-component compositions with other therapeutic and prophylactic agents for anti-viral, anti-tumor, anti-cancer, anti-inflammatory, anti-fungal, antipsoriatic immunosuppressive chemotherapy and restenosis therapy regimens (page 6, lines 12-17).

In contrast, the '968 patent refers solely to radical scavenger compositions comprising, a phenylenediamine derivative or a pharmacologically acceptable salt together with a pharmaceutically acceptable carrier and/or adjuvant effective against brain edema and brain infarction (the '968 patent, col. 1, lines 60-63). The radical scavenger compositions are also said to be effective against various diseases attributable to active oxygen and free radicals (the '968 patent, col. 1, lines 64-67).

There is absolutely no suggestion in the '968 patent that these radical scavenger compositions, let alone compositions "structurally similar" to those radical scavenger compositions, could be used as therapeutic agents for IMPDH related diseases. Thus, the skilled worker would not even consider modifying the compounds or compositions referred to in the '968 patent to read the compositions of the pending claims. Moreover, since

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it is well established that a compound and its properties are inseparable (See, e.g., *In re Papesch*, 315 F.2d 381, 391 (CCPA 1963)), structural modification of one compound or composition into another is unobvious when the modified compound or composition has an inherent, unknown pharmacologically advantageous property. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the obviousness rejection.

Obviousness-Type Double Patenting – U.S. Patent 6,653,309

The Examiner has rejected claims 19, 20 and 36 for obviousness-type double patenting over claim 19 of U.S. Patent 6,653,309 (“the ‘309 patent”). The Examiner acknowledges that the conflicting claims of the instant application are not identical to claim 19 of the ‘309 patent. However, the Examiner alleges that claims 19, 20 and 36 are not patentably distinct from claim 19 of the ‘309 patent because the definition of X in the instant claims overlaps with the corresponding definition in the ‘309 patent and “it is well known to add additional ingredients to any composition to treat a disease”.

Applicants stand ready to file one or more terminal disclaimers, in compliance with 37 C.F.R. §1.321(c), as appropriate to obviate the obviousness-type double patenting rejection upon allowance of any conflicting claims in this application.

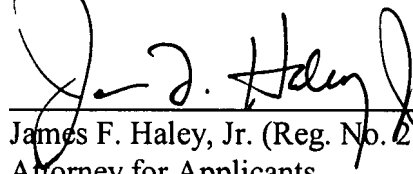


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CONCLUSION

Applicants request that the Examiner consider the above remarks, withdraw the outstanding rejections, and allow the amended claims to issue.

Respectfully submitted,



James F. Haley, Jr. (Reg. No. 27,794)
Attorney for Applicants

c/o Fish & Neave IP Group
ROPES & GRAY LLP
Customer No. 1473
1211 Avenue of the Americas
New York, New York 10036
Tel.: (212) 596-9000
Fax : (212) 596-9090